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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/792,365	03/02/2004	Denise R. Barbut	046,846-010	4265
34263 7590 03/12/2007 O'MELVENY & MYERS LLP 610 NEWPORT CENTER DRIVE 17TH FLOOR NEWPORT BEACH, CA 92660			EXAMINER DIXON, ANNETTE FREDRICKA	
			ART UNIT	PAPER NUMBER
			3771	
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		03/12/2007	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/792,365	BARBUT ET AL.	
	Examiner	Art Unit	
	Annette F. Dixon	3771	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 March 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16,30,31,64,112 and 150 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-16,30,31,64,112 and 150 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>5/4/04, 1/20/06 + 7/10/06</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Drawings

1. The subject matter of this application admits of illustration by a drawing to facilitate understanding of the invention. Applicant is required to furnish a drawing under 37 CFR 1.81(c). No new matter may be introduced in the required drawing. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d).
2. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the inhaler and the chemical structure of the liquid must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an

Art Unit: 3771

application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

3. Applicant is reminded of the proper content of an abstract of the disclosure.

A patent abstract is a concise statement of the technical disclosure of the patent and should include that which is new in the art to which the invention pertains. If the patent is of a basic nature, the entire technical disclosure may be new in the art, and the abstract should be directed to the entire disclosure. If the patent is in the nature of an improvement in an old apparatus, process, product, or composition, the abstract should include the technical disclosure of the improvement. In certain patents, particularly those for compounds and compositions, wherein the process for making and/or the use thereof are not obvious, the abstract should set forth a process for making and/or use thereof. If the new technical disclosure involves modifications or alternatives, the abstract should mention by way of example the preferred modification or alternative.

The abstract should not refer to purported merits or speculative applications of the invention and should not compare the invention with the prior art.

Where applicable, the abstract should include the following:

- (1) if a machine or apparatus, its organization and operation;
- (2) if an article, its method of making;
- (3) if a chemical compound, its identity and use;
- (4) if a mixture, its ingredients;
- (5) if a process, the steps.

Extensive mechanical and design details of apparatus should not be given.

Claim Rejections - 35 USC § 101

4. 35 U.S.C. 101 reads as follows:

Art Unit: 3771

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

5. Claim 64 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Specifically, in claim 64, Applicant recites "a liquid having a boiling point of 38-300 degrees Celsius." The recited liquid is inherently broad and effectively claims the naturally occurring composition of water in aqueous and gaseous forms. Accordingly, claim 64 is considered to be directly related to non-statutory subject matter. No amendment may introduce new matter in the disclosure of an application after its filing date. MPEP §608.04.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1-6, 15, 30-31, 64, and 112 are rejected under 35 U.S.C. 102(b) as being anticipated by Kumar et al. (6,983,749).

As to Claims 1-3, 6, 15, 30 and 64, Kumar discloses a method for transpulmonary cooling comprising the steps of providing a liquid having a boiling point of 38-300 degrees Celsius; nebulizing the liquid to form a mist; and delivering the mist to the airway of the patient so that the patient inhales the mist to cause systemic cooling. (Summary of Invention).

As to Claims 4 and 5, Kumar discloses the liquid or liquid mist is cooled below body temperature and specifically below 10 degrees Celsius. (Column 6, Lines 7-10).

As to Claims 30 and 31, Kumar disclose the perfluorocarbon comprises a fluorinated component and boils below 37 degrees Celsius. (Column 6, Lines 2-6).

As to Claim 112, Kumar discloses a nebulizer as an inhaler device for delivering the medicament to the patient. (Column 6, Lines 7-10).

8. Claims 1-3, 6, 15, 16, 30, 64, 112, and 150 are rejected under 35 U.S.C. 102(b) as being anticipated by Faithfull (6,041,777).

As to Claims 1-3, 6, 15, 16, 30, 64, 112, and 150, Faithfull discloses a closed circuit transpulmonary cooling system utilizing an inhaler to provide a liquid having a boiling point between 38-300 degrees Celsius; nebulizer the liquid to form a mist; and deliver the mist to the airways of the patient to cause systemic cooling. With respect to all claims the patent recites a fluorochemical respiratory promoter and lists a Markush grouping of selected fluorochemical promoters. Two of the respiratory promoters (perfluorodecalin and perfluorooctyl bromide) have boiling points of 142-144 degrees Celsius and 142 degrees Celsius, respectively. Thus these recited respiratory promoters satisfy the instant claim limitation of providing a liquid having a boiling point between 38 and 150 degrees Celsius. Further, the patent recites the use of a nebulizer to deliver the medicament to the user.

Claim Rejections - 35 USC § 103

Art Unit: 3771

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

11. Claims 7-14, and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kumar et al. (6,983,749) in view of Faithfull et al. (6,289,892).

As to Claims 7-14 and 16, Kumar discloses the use of at least one highly fluorinated compound "perfluorocarbon" in the operation of the device. Regarding the structural orientation of the perfluorocarbon, Applicant has not asserted within the disclosure that the structural orientations of the perfluorocarbon provide a particular advantage, solves a stated problem, or serves a purpose different from that of enabling the therapy treatment to be commensurate with the needs of the patient (pediatric, infant, adolescent, adult, or elderly), thus the use of the claimed structural orientations lacks criticality in its utilization, as taught by Faithfull et al. (6,289,892). Therefore, based upon the requirements of the user, it would have been obvious to select a known liquid suitable for the treatment needs of the user.

12. Claim 150 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kumar et al. (6,983,749) in view of Faithfull et al (6,041,777).

As to Claim 150, Kumar discloses a method for transpulmonary cooling, yet does not expressly disclose the method steps of recovering the fluorocarbon from an expired gas; and recirculation the recovered fluorocarbon to the patient. However, at the time the invention was made the use of a closed-circuit ventilation system was well known. Specifically Faithfull discloses the fluorocarbon promoter is utilized to enhance the gaseous exchange of oxygen and carbon dioxide during treatment, thereby aiding in the respiratory treatment (Column 12, Lines 22-55). Therefore, it would have been obvious to one having ordinary skill in the art to modify the device of Kumar to include the recovery step, as taught by Faithfull, to enhance the exchange of gases.

13. Claims 7-14 rejected under 35 U.S.C. 103(a) as being obvious over Faithfull (6,041,777).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed

Art Unit: 3771

in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(I)(1) and § 706.02(I)(2).

As to Claims 7-14, regarding the structural orientation of the fluorochemical, Applicant has not asserted within the disclosure that the structural orientations of the perfluorocarbon provide a particular advantage, solves a stated problem, or serves a purpose different from that of enabling the therapy treatment to be commensurate with the needs of the patient (pediatric, infant, adolescent, adult, or elderly), thus the use of the claimed structural orientations lacks criticality in its utilization. Therefore, based upon the requirements of the user, it would have been obvious to select a known liquid suitable for the treatment needs of the user.

Double Patenting

14. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir.

Art Unit: 3771

1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

15. Claims 1-3, 6, 15, 16, 30, 64, 112, and 150 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 4-8, 17, 18, 20-30, 32, 37-43, 45-51, 54, 60, 62, 63, 65, 68-71, 73-81 of U.S. Patent No. 6,041,777. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant independent claims 1, 64, 112, and 150 are merely broader than the patented claims 1, 17, 32, 45, 60, 71, and 77. The difference lies in the fact that the patent claims include many more elements and steps and is thus more specific. Thus the invention of patented claims 1, 17, 32, 45, 60, 71, and 77 is in effect a "species" of the "generic" invention of instant claims 1, 64, 112, and 150. It has been held that the generic invention is "anticipated" by the "species". See *In Re Goodman*, 29 USPQ2d 2010 (Fed. Cir. 1993). Since claims 1, 64, 112, and 150 are anticipated by claims 1, 17, 32, 45, 60, 71, and 77 of the patent, it is not patentably distinct from patent claims 1, 17, 32, 45, 60, 71, and 77.

With respect to all claims the patent recites a fluorochemical respiratory promoter and lists a Markush grouping of selected fluorochemical promoters. Two of the respiratory promoters (perfluorodecalin and perfluorooctyl bromide) have boiling points of 142-144 degrees Celsius and 142 degrees Celsius, respectively. Thus these recited

Art Unit: 3771

respiratory promoters satisfy the instant claim limitation of providing a liquid having a boiling point between 38 and 150 degrees Celsius. Further, the patent recites the use of a nebulizer to deliver the medicament to the user.

The limitations of claims 2-3, 6, 15, 16, and 30 are recited in patented claims 1, 64, 112, and 150.

Conclusion

16. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The balance of art listed by US patent number relates to inventions capable of performing the method of transpulmonary cooling.


Faithfull et al. (6,289,892), Federowicz et al. (6,694,977), Magers (6,830,581),
Sekins (5,158,536) and Sheppard (3,902,488).

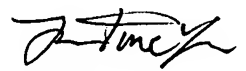
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Annette F. Dixon whose telephone number is (571) 272-3392. The examiner can normally be reached on Monday thru Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on (571) 272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3771

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


Annette F. Dixon
Examiner
Art Unit 3771


JUSTINE R. YU
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700

3/2/07